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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/528,644	03/20/2000	Lars Thim	3951.224-US	5698

7590 11/19/2002

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EXAMINER

ROMEO, DAVID S

ART UNIT	PAPER NUMBER
1647	13

DATE MAILED: 11/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/528,644	THIM ET AL.
	Examiner	Art Unit
	David S Romeo	1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 26 August 2002.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 27-33,36,40 and 41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 27-33,36,40 and 41 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

The request filed on August 26, 2002 (Paper No. 10) for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09528644 is acceptable and a CPA has been established. An action on the CPA follows.

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The amendment filed August 26, 2002 (Paper No. 11) has been entered. Claims 27-33, 36, 40, 41 are pending and being examined. Any objection and/or rejection of record that is not maintained and/or repeated in this Office action is withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Citations by the examiner are in an alphanumeric format, such as "(a1)", wherein the "a" refers to the reference cited on the Notice of References Cited, PTO-892, and the "1" refers to the Paper No. to which the Notice of References Cited, PTO-892, is attached.

Maintained Formal Matters, Objections, and/or Rejections:

15 *Claim Rejections - 35 USC § 112*

Claims 27-33, 36 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

20 Applicants argue that the claim sets forth the configuration of the six disulfide bonds and therefore rises above “minimal structural limitations”. Applicants arguments have been fully considered but they are not persuasive. Although the configuration of the disulfide bonds is set

forth, this configuration sets forth only 12 of a possible 106 residues. The structural limitations are minimal.

Applicants argue that the claim is in compliance with the written description guidelines of the Office, as exemplified by example 9 of the written description guidelines. Applicants' arguments have been fully considered but they are not persuasive. Unlike example 9 of the written description guidelines wherein the complement of SEQ ID NO: 1 was used under highly stringent hybridization conditions (6XSSC and 65 degrees Celsius) for the isolation of cDNAs that were expressed and several were shown to encode proteins that bind to a dopamine receptor and stimulate adenylate cyclase activity, the present application contains no examples wherein the complement of the present application's SEQ ID NO: 2 was used under any hybridization conditions for the isolation of cDNAs that were expressed and shown to encode proteins with spasmolytic activity. The present claims do not require that the homolog have a specific activity or function. Alternatively, Playford (u13), cited by applicants in the response filed December 31, 2001 (Paper No. 8), teaches that porcine SP, the first member of the SP family, obtained its name from its ability to decrease intestinal smooth muscle cell contractility, but that hSP, the polypeptide of the present invention, does not possess this activity.

Applicant argues that hybridization as set forth in Sambrook would be known by one of ordinary skill in the art. Applicants' arguments have been fully considered but they are not persuasive. Stringency varies according to the hybridization conditions and the particular hybrid under study and the limitation "high stringency conditions" does not add further, meaningful structural limitations to the claimed invention.

Applicant argues that Tomasetto discloses the selective hybridization of an hSP probe to genomic DNA in a Southern blot. Applicants arguments have been fully considered but they are not persuasive. The examiner fails to see the significance of this argument because the Southern analysis of human genomic DNA was done to confirm that pS2 and hSP were products of 5 distinct genes and says nothing regarding the isolation of and expression of cDNAs that encode proteins with spasmolytic activity.

Claims 27-33, 36 are rejected under 35 U.S.C. 112, second paragraph, over the recitation of "high stringency conditions". Applicants argue that the phrase would have a clear and definite 10 meaning to one of skill in the art. Applicants arguments have been fully considered but they are not persuasive. The specification fails to provide a limiting definition of "high stringency conditions". Stringency varies according to the hybridization conditions and the particular hybrid under study. One of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the invention. Applicants refer to the pages of Sambrook attached. 15 However, such pages were not attached.

Claims 27-33, 36 are rejected under 35 U.S.C. 112, second paragraph, over the recitation of "homologue". Applicants argue that this rejection is rendered moot by the additional limitations. Applicants arguments have been fully considered but they are not persuasive. The additional limitations, as discussed above, are indefinite.

Double Patenting

Claims 27-33, 36, 40, 41 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8, 10-13 of U.S. Patent No. 5,783,416 (a6). It is acknowledged that Applicants intend to submit a terminal disclaimer 5 when the present application is allowable.

New formal matters, objections, and/or rejections:

Claim Rejections - 35 USC § 112

Claims 27-33, 36, 40, 41 are rejected under 35 U.S.C. 112, first paragraph, as containing 10 subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are directed to or encompass a polypeptide having spasmolytic activity wherein the polypeptide either comprises the amino acid sequence SEQ ID NO: 1 or comprises a 15 homolog, or a homolog of a polypeptide wherein the homolog has no functional limitations. The specification does not disclose an assay for measuring spasmolytic activity. Playford (u13), cited by applicants in the response filed December 31, 2001 (Paper No. 8), teaches that porcine SP, the first member of the SP family, obtained its name from its ability to decrease intestinal smooth muscle cell contractility, but that hSP, the polypeptide of the present invention, does not possess 20 this activity. Accordingly, the present specification has not told the skilled artisan how to make a polypeptide with spasmolytic activity. The skilled artisan is left to extensive, random, trial and error experimentation in order to determine how to use a homolog that does not have a functional

limitation. The skilled artisan is left to extensive, random, trial and error experimentation in order to determine how to make a homolog with spasmolytic activity. The specification lacks guidance for making, and working examples of, a polypeptide or homolog with spasmolytic activity. Moreover, there is a lack of predictability in the art. Predicting structure, hence 5 function, from primary amino acid sequence data is extremely complex and there doesn't exist an efficient algorithm for predicting the structure of a given protein from its amino acid sequence alone. See Bowie (cited by Applicants) page 1306, column 1, full paragraph 1, Ngo (v13) page 433, full paragraph 1, and page 492, full paragraph 2. In view of the breadth of the claims, the limited amount of direction and working examples provided by the inventor, the unpredictability 10 in the art and the quantity of experimentation needed to make or use the invention based on the content of the disclosure, it would require undue experimentation for the skilled artisan to make and/or use the full scope of the claimed invention.

Claims 27-33, 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite 15 for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 27-33, 36 are indefinite because it is unclear if the claimed polypeptide comprises a homolog of SEQ ID NO: 1 or if applicants are claiming a homolog. The metes and bounds are not clearly set forth.

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Conclusion

No claims are allowable.

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (703) 305-4050. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M.

Art Unit: 1647

IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, GARY KUNZ, CAN BE REACHED ON (703) 308-4623.

IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE FOLLOWING TC 1600 BEFORE AND AFTER FINAL RIGHTFAX NUMBERS:

5 BEFORE FINAL (703) 872-9306
 AFTER FINAL (703) 872-9307

IN ADDITION TO THE OFFICIAL RIGHTFAX NUMBERS ABOVE, THE TC 1600 FAX CENTER HAS THE FOLLOWING OFFICIAL FAX NUMBERS: (703) 305-3592, (703) 308-4242 AND (703) 305-3014.

10 CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (703) 308-0294.

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.

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DAVID ROMEO
PRIMARY EXAMINER
ART UNIT 1647

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DSR
NOVEMBER 17, 2002